Partnering with Patients to Find Adverse Events

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ABSTRACT

Purpose. The goal of this study was to understand the role of patients in identifying adverse events.

Scope. Although adverse events are prevalent in healthcare, existing methods for measuring them are limited. We studied adult inpatients at a Boston teaching hospital and its primary care network in order to understand the feasibility of patient-reported incidents and to characterize these reports.

Methods. We completed 528 interviews of 229 adult medical inpatients and reviewed their medical records. A physician panel classified adverse events and service quality incidents. We also examined medical records of a sample of 267 of 1821 outpatients who opened an electronic medication safety message.

Results. Inpatients reported adverse events at a rate of 8.7% and near-miss errors at a rate of 5.7%. None were reported in the hospital incident reporting system; 39% of patients reported service quality incidents. The presence of any service quality deficiency more than doubled the odds of any adverse event or error (adjusted OR 2.5, 95% CI 1.2–5.4). In addition, we found that adult primary care patients and physicians responded promptly to patient-directed electronic medication safety messages, identifying and addressing a variety of medication-related problems.

Key Words. Patient safety, medical error, patient-physician communication, information technology.

PURPOSE

The overall goal of this study was to understand the role that patients can play in identifying adverse events. The project included three substudies. The first relied on inpatients to report on the incidence and type of medical errors they experienced; its objective was to describe the epidemiology of patient-reported medical errors among inpatients. The second substudy assessed whether ambulatory patients can identify adverse drug events through an internet-based electronic mail query. This substudy would help characterize the prevalence and type of outpatient adverse drug events and assess the value of patient reporting as a mechanism to improve the quality of care. The third project focused on the hospital, rather than patient, as unit of analysis and aimed to assess whether organizations that provide patient-centered care also produce fewer complications than expected.

The specific aims of the study were framed as follows:

1) To assess whether hospitalized patients and their families can identify adverse events (AEs) and medical errors, to characterize the epidemiology of patient-

reported events and errors, and to compare patient-reported events with the results of other methods.

2) To assess whether ambulatory patients can identify adverse drug events (ADEs) and medication errors in response to automatic electronic queries, to characterize the epidemiology of patient-reported ADEs and medication errors, and to understand whether patient ADE reporting results in timely and appropriate responses by primary care physicians.

3) To examine whether hospital performance on a consumer survey of quality healthcare correlates with surgical complication rates.

SCOPE

Background. Medical error is prevalent in healthcare. The Institute of Medicine's 1999 report, *To Err is Human*, echoed and amplified this concern, citing up to 98,000 unnecessary deaths and 1,000,000 excess injuries per year in the US [1]. Despite the intense public interest generated in response to the IOM report, information about the prevalence and consequences of medical error has been, until recently, surprisingly thin, particularly in ambulatory and specialty care settings [2]. The intensity of debate reflects the scarcity of reliable data about medical error: high-quality studies are limited to a few hospitals, conditions, and clinical settings [2].

A limitation of large population-based studies of medical error is their reliance on medical record review [3-5]. Observational methods yield higher error rates than chart review, but direct observation of clinician's performance is an unwieldy method for error measurement [6]. Sophisticated computer physician order-entry systems, another error measurement tool, are not widely available [7-8]. Hospital-based incident reports and sentinel event reports underestimate error rates by an order of magnitude, perhaps because clinicians have few incentives to report [9]. Automated screening algorithms that rely on administrative data are limited to a few conditions and require secondary clinician review [10].

A potentially promising approach to the study of medical harm enlists the help of patients and their families. Patients may make valuable partners in identifying medical errors for several reasons. First, patients have direct and immediate access to subjective data about their healthcare and response to therapy. Second, patients and their families are motivated and attentive observers. Clinicians, in contrast, must divide their attention among many patients. Third, patients and their families may have health information about recent care at another local facility or out of town. Fourth, patients may notice irregularities that clinicians fail to observe or take for granted (e.g., delayed lunch for a brittle diabetic, failure to receive "as needed" pain medication). Fifth, patients may be the first to note differences of opinion among members of the care team. Patient participation in monitoring care may improve adherence to physicians' recommendations.

Consumer surveys of healthcare quality show that patients provide valuable information about quality in healthcare, and at a reasonable cost [11]. Patients identify dimensions of quality that clinicians may not recognize or emphasize, including emotional support, information and education, involvement of family and friends, coordination of care among providers, and continuity of care [12-13].

Accordingly, the overall objective of this study was to explore the role that patients and their families can play in identifying, understanding, and mitigating error. I sought to address several related questions: Can patients identify adverse events and potential adverse events? What types of adverse events and errors to patients report? Do patient reports of adverse events and errors affect the quality of care? Do organizations that deliver patient-centered care produce fewer than expected complications?

Context. In preliminary studies, my colleagues and I found that communication lapses contributed importantly to preventable and ameliorable adverse drug events in adult primary care [14]. Among 661 patients whose medical records we reviewed and whom we interviewed at 10 days and 3 months after the index visit, we identified almost 90% of adverse drug events by interview rather than chart review. Furthermore, in about one quarter of medication errors (preventable and potential ADEs), patients had more severe or prolonged symptoms than they should have experienced because the patient failed to report a complication or side effect to the physician. In almost half of medication errors, the patient experienced more severe or prolonged symptoms that they should have experienced because the clinician failed to act on information that the patient provided.

We also found that informal interviews of clinicians could increase the yield of incident reports, particularly reports that were enriched in serious and preventable events [15]. We reasoned that a similar approach might serve as a model for patient reporting.

METHODS

This study used a variety of methods, aligned with each aim. For Aim #1, we conducted a prospective cohort study of medical inpatients at a teaching hospital; 229 (87%) of 264 eligible patients agreed to participate and completed 528 in-person interviews during their hospitalization. We reviewed patients' medical records as well as hospital incident reports. We used a physician panel to ascertain the presence of adverse events and service quality incidents and to classify the type of event and its severity and preventability. The limitation of this approach is that some patients were too ill to participate, and the study was conducted at a single teaching hospital.

For Aim #2, we conducted a pilot study of a cohort of adult patients enrolled in a patient internet portal at three primary care practices affiliated with a teaching hospital. MedCheck, a medication safety application, sent patients a secure electronic message 10 days after they received a new or changed prescription. MedCheck asked if the patient had filled the prescription or experienced medication-related problems and then forwarded the patient's response to their primary care physician. We selected a stratified random sample of 267 from 1821 patients who received and opened a

MedCheck message from April 2001 to June 2002. We reviewed medical records for 3 months following their first MedCheck message. We analyzed patient and clinician response rates and times, examined patient-clinician communication about medications, and identified ADEs.

We also performed a randomized, controlled trial of the MedCheck intervention involving 796 patients who completed an electronic informed consent online. We completed follow-up interviews with 649 patients (82%) and chart reviews. A physician panel completed classification of candidate adverse, and data analysis is ongoing. A limitation of the MedCheck studies was the use of a single portal serving one health system; another was the self-selection of health-literate and technologically sophisticated patient participants.

Although the Massachusetts Hospital Association and Massachusetts Healthcare Quality Partnership supported the project outlined in Aim #3 of the original proposal, the MHA/MHQP abandoned the regular use of Picker surveys in Massachusetts at the beginning of the study period. In addition, the Complications Screening Program was supplanted by the AHRQ Patient Safety Indicators as an administrative tool for measuring adverse events. Regrettably, no formal arrangement was feasible with the vendor of the Picker instrument during the grant period, and the H-CAHPS survey was not yet available publicly. Resources that would have been used for this project were used instead to support work on Aims #2 and #3 and related projects.

RESULTS

Principal Findings. The principal finding of Aim #1 was to document the capacity of hospitalized patients to identify adverse events affecting their care and to characterize these events. Conducting surveys of medical inpatients, we found that 17 patients (7%) experienced 20 adverse events, for an adverse event rate of 8.7% [16]. One event was serious. Eight patients (4%) experienced 13 potential adverse events (6%), for a near-miss error rate of 5.7%. Five events were serious or life threatening. Eleven (55%) of 20 adverse events and four (31%) of 13 potential adverse events were documented in the medical record, but none were found in the hospital incident reporting system. Patients with three or more drug allergies were more likely to report errors compared to patients without drug allergies (IRR 4.8, 95% CI 1.7-13.5).

In a related study using the same patient cohort, we examined the service quality problems that patients reported during the daily interviews [17]. We found that 39% of 228 patients experienced 157 service quality incidents during the admission, for a rate of 68.9 incidents per 100 admissions. The most common service quality problems involved waits and delays (n=45), problems with communication between staff and patients (n=36), environmental issues and amenities (n=35), coordination of care (n=21), poor interpersonal skills (n=20), and lack of respect for patient needs and preferences (n=18). Patients with service quality incidents were more likely to describe the hospitalization as other than excellent (adjusted OR 1.8 for each additional incident, 95% CI 1.3-2.5).

In a third study of the same patient cohort, we analyzed the relationship between service problems and adverse events [18]. A research nurse completed 229 detailed chart reviews, blinded to patients' reports of errors and adverse events, and a physician panel classified candidate adverse events identified on nurse review. In this study, of the 52 incidents identified on chart review, patients experienced 34 adverse events, 11 close calls, and seven low-risk errors. The presence of any service quality deficiency more than doubled the odds of any adverse event, close call, or low-risk error (adjusted OR 2.5, 95% CI 1.2–5.4). Service quality deficiencies involving poor coordination of care (adjusted OR 4.4, 95% CI 1.4–14.0) were associated with the occurrence of adverse events and medical errors. We concluded that patient-reported service quality deficiencies were associated with adverse events and medical errors. Patients who report service quality incidents may help identify patient safety hazards.

The findings of Aim #2 extended those of Aim #1. In Aim #2, we examined the role of a patient internet portal-based intervention to improve patient-doctor communication and adverse drug events. The pilot project for this study found that patients opened 79% of MedCheck messages and responded to 12%; 77% responded within 1 day [19]. Patients often identified problems filling their prescriptions (48%), problems with drug effectiveness (12%), and medication symptoms (10%). Clinicians responded to 68% of patients' messages; 93% answered within 1 week. Clinicians often supplied or requested information (19%), or made multiple recommendations (15%). Patients experienced 21 total adverse drug events; they reported 17 electronically. We concluded that patients and physicians responded promptly to patient-directed electronic medication messages, identifying and addressing medication-related problems, including adverse drug events. As with the inpatient study in Aim #1, Aim #2's adult primary care cohort was also able to report medication-related symptoms in a timely way and in a way that prompted appropriate responses from their caregivers.

Discussion and Conclusion. The implication of this series of studies was to demonstrate that hospitalized patients can provide information about adverse events and quality of care that is not captured through usual research methods (such as chart review) or administrative tools (such as hospital incident reports). In addition, the relationship between service quality and patient safety may offer a promising area of future investigation. If the safety climate in an organization supports effective communication and efficient care, this may manifest itself as favorable patient ratings of service quality as well as fewer medical errors and preventable adverse events.

In addition, the lessons from inpatient care appear to hold in the ambulatory setting. Using email prompts via a patient internet portal, adult primary care patients can (and did) report medication-related symptoms including adverse drug events. Electronic medication safety reminders prompted a meaningful dialogue between patients and their clinicians, addressing a variety of issues and potential problems in medication safety.

Significance and Implications. Incidents elicited from patients include events that are unknown to clinicians and to the healthcare organization. These events appear to be enriched in severe and preventable events, at least in the inpatient setting. Eliciting

incidents from patients may offer a source of information about error and medical injury that complements other measurement techniques and affords researchers and healthcare leaders information about patient safety. This approach has proved to be generalizable to settings outside of adult primary care. In a subsequent study at a comprehensive cancer center, we found that 22% of patients report an episode of "unsafe care" in the previous month [20]. The cost effectiveness of an approach to patient safety that incorporates patient and family participation requires more study. However, our work offers proof of principle that many patients have the capacity to identify medical errors and adverse events and to report them in a timely enough way to affect, and perhaps enhance, their care.

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